

Appendix D

Menstrual Tampon Substantial Equivalence Comparison Chart

| Comparison Element | New Device | Predicate Device(s) |
|--|------------|---------------------|
| Device Name | | |
| Manufacturer | | |
| 510(k) Number | | |
| Intended Use | | |
| Device Design (e.g., shape/size of tampon & applicator) | | |
| Component Materials | | |
| Dimensions <ul style="list-style-type: none">• Length• Diameter | | |
| Absorbency(grams), <ul style="list-style-type: none">• Maximum• Minimum | | |
| Required Accessory Devices, if any | | |
| Other Features | | |